SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Stent, SFA

Device Trade Name: Complete® SE Vascular Stent System

Device Procode: NIP

Applicant's Name and Address: Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403
USA

Date(s) of Panel Recommendation: none

Premarket Approval Application (PMA) Number: P110040

Date of FDA Notice of Approval: September 19, 2013

II. INDICATIONS FOR USE

The Complete SE Vascular Stent System is indicated to improve luminal diameter in symptomatic patients with *de novo* and/or restenotic lesions or occlusions of the superficial femoral artery (SFA) or proximal popliteal artery (PPA) with reference diameters ranging from 4 mm to 7 mm and lesion lengths up to 140 mm.

III. CONTRAINDICATIONS

The Complete SE Vascular Stent System is contraindicated in:

- patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system
- patients who cannot receive antiplatelet or anticoagulation therapy

IV. WARNINGS AND PRECAUTIONS

The Warnings and Precautions can be found in the Complete SE Vascular Stent System labeling (Instructions For Use).

V. DEVICE DESCRIPTION

The Complete SE Vascular Stent System is used to deliver a self-expanding stent to the superficial femoral/proximal popliteal arteries via a sheathed delivery system. The system is comprised of two main components: the implantable vascular stent (Figure 1) and the disposable delivery system (Figure 2). The stent is compressed and preloaded into the delivery system and advanced to the target lesion, where the protective sheath is retracted. Upon deployment, the stent self-expands to provide a vessel support frame and to impart an outward radial force on the arterial lumen to establish patency.

The Complete SE stent is constructed of a medical grade nickel-titanium alloy (Nitinol) and has 4 tantalum radiopaque markers on each end to aid in visualization and facilitate placement. It is radially compressed and loaded into a 6F compatible OTW delivery system with a working length of either 80 cm or 130 cm that is compatible with a 0.035 in (0.89 mm) guidewire. The stent is positioned to the intended lesion site and then deployed by retraction of a protective sheath. Upon deployment, the stent self-expands to provide a vessel support frame and to impart an outward radial force on the arterial lumen to establish patency. The stent remains as a permanent implant. There are four radiopaque markers at each end.

The stent design for the SFA/PPA indication incorporates varying segment lengths of 2.0 and 2.25 mm for diameter families of 5 mm to 6 mm and 7 mm to 8 mm, respectively. The stents are offered in lengths of 20, 40, 60, 80, 100, 120 and 150 mm to accommodate various lesion lengths (up to and including 140 mm). Additional details and recommended device sizing can be found in the Complete SE Vascular Stent System Instructions For Use (IFU).

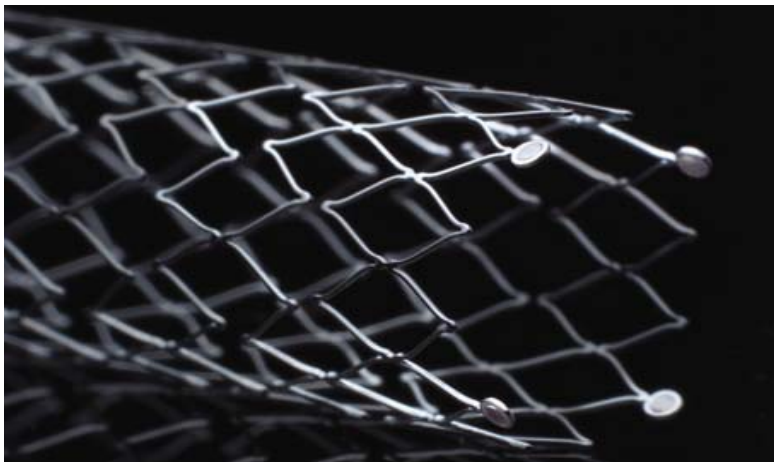
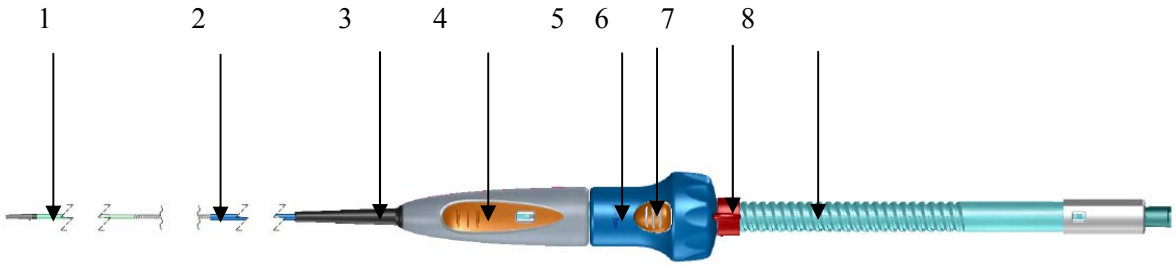


Figure 1: Complete SE Stent with Tantalum Markers



1	Tip and Flexible Outer Member Sheath	5	Rotation Direction Arrows
2	Outer Stability Member	6	Deployment Rotation/Slider Mechanism
3	Strain Relief	7	Safety Lock
4	Front Grip	8	Screw Gear

Figure 2: Complete SE Vascular Stent Delivery System

The Complete SE device indicated for the treatment of SFA/PPA will be offered in various lengths and diameters.

Table 1: Complete SE Size Matrix – SFA/PPA Indication

Length / Diameter	20mm	40mm	60mm	80mm	100mm	120mm	150mm
5 mm	x	x	x	x	x	x	x
6 mm	x	x	x	x	x	x	x
7 mm	x	x	x	x	x	x	x
8 mm	x	x	x	x	x	x	x

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of superficial femoral and proximal popliteal artery atherosclerotic disease:

- Non-invasive treatment (e.g., exercise, smoking cessation and/or drug therapy)
- Minimally invasive treatment (e.g., balloon angioplasty, endovascular stent or stent-graft placement, directional atherectomy)
- Surgical treatment (e.g., surgical bypass)

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

Currently, the Complete SE Vascular Stent System is commercially available outside the US (OUS), including Asia, Europe and Latin America. The Complete SE Vascular Stent System for the treatment of lesions in the superficial femoral artery (SFA) or the proximal popliteal artery (PPA) has been available in Western Europe and other OUS geographies since January 2013. No products have been withdrawn from the market in any country for any reason.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

Table 2: Potential Adverse Effects

• Abrupt stent closure	• Myocardial infarction
• Allergic reaction (contrast medium; drug; stent or filter material)	• Occlusion of SFA/PPA or distal vasculature
• Amputation or limb loss	• Pain (leg or foot)
• Aneurysm or pseudoaneurysm in vessel or at vascular access site	• Pain at catheter insertion site
• Angina or coronary ischemia	• Pulmonary embolism
• Arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation)	• Renal failure or insufficiency, secondary to contrast medium
• Asystole or bradycardia, requiring placement of a temporary pacemaker	• Restenosis of vessel in stented segment
• Arteriovenous fistula	• Stent malposition, or migration, which may require emergency surgery to remove stent
• Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention	• Stent strut fracture
• Death	• Stent thrombosis or occlusion
• Detachment of a system component or implantation of an unintended site	• Stroke
• Emboli, distal (for example, air, tissue, plaque, ~~or~~ thrombotic material, or stent)	• Vascular thrombosis or occlusion at puncture site, treatment site, or remote site
• Emergent bypass surgery to perfuse limb	• Vessel dissection, perforation or rupture
• Fever	• Vessel spasm or recoil
• Hematoma at vascular access site, with or without surgical repair	
• Hypotension or hypertension	
• Infection, local or systemic, including bacteremia or septicemia	
• Ischemia requiring intervention (bypass or amputation of toe, foot, or leg)	

For the specific adverse events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF PRE-CLINICAL STUDIES

A. Summary of Biocompatibility Testing

The biocompatibility of the Complete SE Vascular Stent System was evaluated per the requirements of the AAMI/ISO 10993. Tests were conducted on the finished, sterile Complete SE Vascular System. All biocompatibility testing was conducted in compliance with applicable requirements in the Good Laboratory Practice (GLP) in 21 CFR 58.

The test methods conducted to support the Complete SE delivery system were appropriate for an externally communicating device having contact with circulating blood for a limited (<24 hour) exposure (the delivery system) and for an implant device with permanent (>30days) blood contact (the SFA stent). All test results met the acceptance criteria and indicate that the Complete SE Vascular Stent System is biocompatible.

Table 3: Summary of Complete SE Biocompatibility Testing

ISO 10993 Biological Effect Category	Test Method	Test Article	
		Complete SE Stent[α]	Complete SE Delivery System[β]
Cytotoxicity	MHLW Cytotoxicity, Colony Assay Method (Extraction)	Pass (Non-toxic)	Pass (Non-toxic)
	ISO MEM Elution Cytotoxicity	Pass (Non-toxic)	Pass (Non-toxic)
Sensitization	MHLW Maximization Sensitization		Pass (Non-sensitizing)
	ISO Maximization Sensitization	Pass (Non-sensitizing)	Pass (Non-sensitizing)
Irritation / Intracutaneous	ISO Intracutaneous Reactivity	Pass (Non- irritant)	Pass (Non- irritant)
Acute Systemic Toxicity	MHLW Acute Systemic Toxicity	Pass (Non-toxic)	Pass (Non-toxic)
	ISO Acute Systemic Toxicity	Pass (Non-toxic)	Pass (Non-toxic)
	USP Material Mediated Pyrogen	Pass (Non-pyrogenic)	Pass (Non-pyrogenic)
Subchronic Toxicity/ Implantation	4-wk Systemic Toxicity Implantation	Pass (Non-toxic)	
	13-wk Systemic Toxicity Implantation	Pass (Non-toxic)	
Genotoxicity	Bacterial Reverse Mutation Study	Pass (Non-genotoxic)	
	In-vivo Mouse Peripheral Blood Micronucleus Study	Pass (Non-genotoxic)	
	Mouse Lymphoma Assay	Pass (Non-genotoxic)	
Hemocompatibility	ISO (modified ASTM method) *In-vitro* Hemolysis,	Pass	

ISO 10993 Biological Effect Category	Test Method	Test Article	
		Complete SE Stent[α]	Complete SE Delivery System[β]
	Indirect Method	(Non-hemolytic)	
	ASTM *In-vitro* Hemolysis (indirect and direct contact)		Pass (Non-hemolytic)
	MHLW *In-vitro* Hemolysis	Pass (Non-hemolytic)	Pass (Non-hemolytic)
	Complement Activation, C3a and SC5b-9	Pass (Non-activator)	Pass (Non-activator)
	In-vivo Thromboresistance	Pass (Non-thrombogenic)	Pass (Non-thrombogenic)
[α] Blood contact duration: permanent (> 30 days)			
[β] Circulating blood contact duration: limited exposure (< 24 hours)			

B. Summary of *In Vitro* Testing

The non-clinical testing was originally carried out in accordance with the 2005 FDA Guidance Document, *Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems,* and later re-assessed for compliance with the 2010 FDA Guidance Document and ISO 25539-1 *Cardiovascular Implants Endovascular Devices: Part 1: Endovascular Prostheses*.

In vitro testing was conducted on appropriate sizes. The testing conducted applied to the entire range of stent sizes of the Complete SE product offering.

Table 4: *In vitro* Test Results Summary

Test	Purpose	Acceptance Criteria	Test Results
Material Composition – Stent	To ensure the composition conforms to ASTM F2063-00 for medical grade Nitinol.	Must meet all material specifications listed in specifications	CERTIFIED The materials met the industry standards.
Material Composition – Delivery System	To ensure consistent material performance.	Must meet all material specifications	CERTIFIED The materials met the industry standards.
Shape Memory and Superelasticity of Intravascular Stents -- Austenite Finish Temperature (A_f)	To ensure comparable final stent *in-vivo* performance over the entire size matrix the total range of Af temperature allowed in manufacturing over all diameters must be limited.	4mm-5mm @ 15.0°C to 24.2°C 6mm - 8mm @ 16.2°C to 26.2°C	The acceptance criteria were met

<table>
<tr><th>Test</th><th>Purpose</th><th>Acceptance Criteria</th><th>Test Results</th></tr>
<tr><td>Stent Corrosion Resistance
-- Fretting</td><td>To ensure the stent material maintains its mechanical properties after implant the material must not break down significantly after implant.</td><td>For Information Only
The purpose of this test is to provide a relative comparison of corrosion behavior between Complete SE stents and the commercially available Cordis SMART Control stent.</td><td>Complete SE showed comparable or better fretting corrosion resistance than a known commercially available control.</td></tr>
<tr><td>Stent Corrosion Resistance
-- Pitting & Crevice
-- Galvanic</td><td>To ensure the stent material maintains its mechanical properties after implant the material must not break down significantly after implant.</td><td>The purpose of this test is to provide a relative comparison of corrosion behavior between Complete SE stents and the commercially available Cordis SMART Control stent.</td><td>Complete SE showed comparable or better pitting, crevice, and galvanic corrosion resistance than known commercially available control.</td></tr>
<tr><td colspan="4">Stent Dimensional & Functional Attributes</td></tr>
<tr><td>Dimensional Verification
-- Self-Expanding Stent (Inner Diameter)</td><td>The stent must deploy to a predictable diameter in order to ensure appropriate treatment of the target vessel.</td><td>5mm: 4.75 – 5.36
6mm: 5.74 – 6.35
7mm: 6.68 – 7.39
8mm: 7.65 – 8.46</td><td>The acceptance criteria were met</td></tr>
<tr><td>Dimensional Verification
-- Stent Length</td><td>To ensure the stent maintains its mechanical performance throughout production its dimensions must be carefully controlled.</td><td>
<table>
<tr><th>Size (Φ x L)</th><th>Length (mm)</th><th></th><th>Size (Φ x L)</th><th>Length (mm)</th></tr>
<tr><td>5x20</td><td>21±3</td><td></td><td>5x80</td><td>84±6</td></tr>
<tr><td>6x20</td><td>21±3</td><td></td><td>6x80</td><td>81±6</td></tr>
<tr><td>7x20</td><td>21±3</td><td></td><td>7x80</td><td>81±6</td></tr>
<tr><td>8x20</td><td>21±3</td><td></td><td>8x80</td><td>81±6</td></tr>
<tr><td>9x20</td><td>20.5±3</td><td></td><td>5x100</td><td>105±8</td></tr>
<tr><td>10x20</td><td>20.5±3</td><td></td><td>6x100</td><td>101±8</td></tr>
<tr><td>5X40</td><td>43±4</td><td></td><td>7x100</td><td>104±8</td></tr>
<tr><td>6X40</td><td>41±4</td><td></td><td>8x100</td><td>102±8</td></tr>
<tr><td>7X40</td><td>41±4</td><td></td><td>5x120</td><td>125±10</td></tr>
<tr><td>8X40</td><td>40.5±4</td><td></td><td>6x120</td><td>120±10</td></tr>
<tr><td>9X40</td><td>42±4</td><td></td><td>7x120</td><td>124±10</td></tr>
<tr><td>10X40</td><td>41±4</td><td></td><td>8x120</td><td>121±10</td></tr>
<tr><td>5X60</td><td>62±5</td><td></td><td>5x150</td><td>155±12</td></tr>
<tr><td>6X60</td><td>60±5</td><td></td><td>6x150</td><td>148±12</td></tr>
<tr><td>7X60</td><td>61±5</td><td></td><td>7x150</td><td>150±12</td></tr>
<tr><td>8X60</td><td>59.5±5</td><td></td><td>8x150</td><td>147±12</td></tr>
</table>
</td><td>The acceptance criteria were met</td></tr>
<tr><td>Stent Percent Metal Coverage
Percent Surface Area</td><td>To determine the amount of metal that comes into contact with the vessel wall. This may affect the biological response of the vessel to the stent.</td><td colspan="2">For Information Only
The Percent Metal Coverage was calculated.
5mm: 13.6% to 8mm: 9.9%</td></tr>
<tr><td>Foreshortening</td><td>To determine how the Complete SE performs against leading competitors.</td><td>Stent Percent Foreshortening (% max)
5mm: ≤10
6mm: ≤10
7mm: ≤10</td><td>The acceptance criteria were met</td></tr>
</table>

Test	Purpose	Acceptance Criteria	Test Results
		8mm: ≤10	
Recoil for Balloon Expandable Stents	N/A	Not required for self-expanding stents	
Stent Integrity (Deployed Stent Conformation)	To determine the overall appearance and shape of the stent after being deployed from the delivery system. The final deployed shaft of the stent is critical to the clinical effectiveness of the stent.	Stent must be straight, and of consistent diameter. Any damage, twisting, bent or broken struts, and any unusual stent configuration are not allowed when viewed at 7X magnification. Cracks, fractures, and rough/sharp edges are not allowed when viewed at 45X.	The acceptance criteria were met
Radial Stiffness and Radial Strength	N/A	Not applicable to Self-Expanding Stents (see result for Radial Force)	
Stent Crush Strength (Radial Resistive Force)	To determine if, after deployment, the stent maintains patency after being compressed. The crush strength should be comparable to previous devices and competitors.	Stent Crush Strength (lbf) 5mm: 1.28 – 2.70 6mm: 1.28 – 2.70 7mm: 1.20 – 2.95 8mm: 1.05 – 2.88	The acceptance criteria were met
Radial Outward Force (During Expansion)	The stent must maintain contact with the vessel wall throughout its indicated size rage.	For Information Only 5mm: 23.1N to 27.0N 6mm: 20.9N to 22.7N 7mm: 20.0N to 23.0N 8mm: 19.6N to 23.4N	
Mechanical Properties -- Mechanical properties of raw materials	To ensure the composition conforms to ASTM F2063-00 for Medical Grade Nitinol.	See **A1**. Material Composition - Stent	
Mechanical Properties -- Post-processing mechanical properties	To ensure the composition conforms to ASTM F2063-00 for medical grade Nitinol. Additionally, to collect data that will inform the finite element analysis (FEA).	(See B.9, *Stress Analysis for gait loading* and B.10, *Stress Analysis for radial loading*)	
Stress Analysis (FEA) and Fatigue Analysis – Overlapped and Non-Overlapped	The purpose of the stress analysis is to confirm the structural integrity and long term endurance of the stent under clinically relevant loading conditions.	The analysis must indicate a design safety factor greater than 1.0 for the following conditions: -pulsatile -axial shortening -torsion -bending	The acceptance criteria were met with a safety factor greater than 1.0
Accelerated Durability Testing - Bent Radial Fatigue (Overlapped and Non-Overlapped)	The purpose of fatigue testing is to confirm the structural integrity and long term endurance of the stent under clinically relevant loading conditions.	The stent must not exhibit any segment detachment during accelerated bent radial fatigue testing equivalent to an implant life of 10 years (420 million cycles).	The acceptance criteria was met under multi-mode test conditions; no fractures were observed

Test	Purpose	Acceptance Criteria	Test Results
Accelerated Durability Testing (Overlapped Multi-Mode Fatigue)	The purpose fatigue testing is to confirm the structural integrity and long term endurance of the stent under clinically relevant loading conditions.	The stent must not exhibit any segment detachment during accelerated fatigue testing equivalent to an implant life of 10 years (10 million cycles) under the following conditions: -axial shortening -torsion -bending.	The acceptance criteria was met under aggressive multi-mode test conditions
Accelerated Durability Testing, Multi-Mode Fatigue (Sitting/Stair Climbing)	The purpose fatigue testing is to confirm the structural integrity and long term endurance of the stent under clinically relevant loading conditions.	The stent must not exhibit any segment detachment during accelerated fatigue testing equivalent to an implant life of 10 years (750,000 cycles) under the following conditions: -axial shortening -torsion -bending.	The lumen and overall stent integrity were maintained throughout testing.

Test	Purpose	Acceptance Criteria	Test Results
Particulate Evaluation		Different sizes of this same device already have PMA approval for use in the iliac arteries. The end organs impacted by the iliac and SFA vessels are the same. Therefore, the complication rate of adverse events due to particulate generation of the SFA intended device is not expected to be greater than the rate associated with the iliac device. Thus no additional testing was needed.	
MRI Safety & Compatibility	To empirically confirm the conditions by which the Complete SE may be safely used within an MR field.	The device must be MR Conditional (ASTM F2503) with respect to implant radiofrequency (RF) heating (ASTM F2182), magnetically induced translation (ASTM F2052) or magnetically induced torque (ASTM F2213) upon subjection to 1.5 Tesla or 3 Tesla magnetic field. The MRI may affect the quality of the diagnostic information (ASTM F2119). The MR conditions in which the device was tested are specified in the IFU.	The Complete SE is suitable for MR Conditional Labeling, per ASTM F2503.
Radiopacity	To determine if the Complete SE Stent and Delivery System are visible using standard fluoroscopic guidance.	Visibility of stent markers under fluoroscopy must be qualitatively comparable to commercially available Nitinol stents with radiopaque markers.	The stents were determined to have visibility under X-Ray and fluoroscopic imaging that is comparable to other commercial stents
Stent Crush Resistance	Determine if, after deployment, the stent maintains patency after a clinically relevant crush load has been applied.	The stents must meet the design specification for stent integrity - the stents should not exhibit damage - twisting, bent elements, broken struts or any unusual configuration - after being deployed then crushed.	The acceptance criteria were met
Stent Kink Resistance	Determine if the stent kinks when subjected to angulation or bending.	For Information Only The Complete SE stent does not kink when subjected to a bend radius as small as 0.0mm.	
In-Stent Restenosis	N/A	Not applicable – per the IFU, Complete SE is only intended to be used in previously unstensted lesions	
Stents Intended for Coronary Bifurcation Lesions	N/A	Not applicable	
Delivery System Dimensional & Functional Attributes			
Dimensional Verification Delivery System (Catheter) Working Length	The purpose of this test is to determine if the catheter length can reliably meet the intended design specification.	130 ± 2.5 cm for long catheters; 80 cm ± 2.5 cm for short catheters	Long Delivery System The acceptance criteria were met Short Delivery System The acceptance criteria were met
Dimensional Verification Marker Band Spacing	The purpose of this test is to determine if the catheter dimensions can reliably meet the intended design specification.	The gap between the RO marker(s) and stent (either proximal or distal to stent) must be 0 to 1.5mm	The acceptance criteria were met
Dimensional	The purpose of this test is	The maximum device crossing profile	The acceptance

Test	Purpose	Acceptance Criteria	Test Results
Verification Crossing Profile	to ensure the device will fit in the intended introducer sheath and anatomy.	at the tip, at the 6F section and at the stability member, is not greater than 0.084".	criteria were met
Delivery, deployment, & retraction Deployment Force	To determine if the delivery system will safely deploy the stent without the risk of shaft or bond failure.	lb max Diameters 5-8mm x ≤ 80mm length: 6lbs Diameters 5-8mm x ≥ 100mm length: 7lbs	The acceptance criteria were met
Delivery, deployment, & retraction Deployment Accuracy	To determine if the stent is capable of being deployed to a target location.	+7.0mm to - 7.0mm NOTE: without active correction	The acceptance criteria was met; the average distance from an intended deployment target was 0.8mm
Balloon Rated Burst Pressure (Balloon expandable stents only)	N/A	Not required for self-expanding stents	
Balloon Fatigue (Balloon expandable stents only)	N/A	Not required for self-expanding stents	
Balloon Compliance – Stent Diameter vs. Balloon Pressure (Balloon expandable stents only)	N/A	Not required for self-expanding stents	
Balloon Inflation and Deflation Time (Balloon expandable stents only)	N/A	Not required for self-expanding stents	
Catheter Bond Strength			
Bond 01 – Tip to inner member (Tip Pull)	To determine if the strength of the catheter is sufficient for device tracking, stent implantation and delivery system removal.	Refer to C.8, Tip Pull Test (Tip to Inner Member Bond Strength)	
Bond 02 – Inner member to middle member		2.5 lbf min	The acceptance criteria were met
Bond 03 – Middle member to hypotube/inner member		2.5 lbf min in tension 4.6 lbf in compression	The acceptance criteria were met
Bond 04 – Inner member to luer		2.5 lbf min	The acceptance criteria were met
Bond 05 – Hypotube to luer		2.5 lbf min in tension 4.6 lbf in compression	The acceptance criteria were met
Bond 06 – T-tube to outer member		7.0 lbf min	The acceptance criteria were met
Bond 07 –Strain relief to stability member		3.4 lbf min	The acceptance criteria were met
Outer member 6F section		5.0 lbf min	The acceptance criteria were met

Test	Purpose	Acceptance Criteria	Test Results
Tip Pull Test (Tip to Inner Member Bond Strength)		2.5 lbf min	The acceptance criteria were met
Trackability	To determine if the device can successfully track through a simulated vessel to a target location.	The trackability mean of the "worst case" Complete SE devices (10x80mm, 8x150mm) must be less than 450 gf.	The acceptance criteria were met

C. Sterilization

The Complete SE Vascular Stent System is supplied sterile. Complete SE is sterilized using E-beam sterilization in accordance with ANSI/ AAMI/ ISO11137, TIR29 and Medtronic Vascular internal quality control procedures. All testing performed verified that Complete SE can be sterilized at a minimum of 25 kGy to successfully achieve a Sterility Assurance Level (SAL) of 10^{-6}.

D. Packaging and Shelf Life

The Complete SE aged packaging underwent shipping simulation. The Complete SE packaging configuration has met all requirements for sterile barrier integrity, pouch seal strength, and visual acceptance criteria indicating that the packaging would remain acceptable for the 2-year shelf life of the Complete SE Vascular Stent System. Additionally, the performance characteristics and specifications of the finished device that may be affected by aging were evaluated. This testing also demonstrated that the Complete SE device would remain acceptable for the 2-year shelf life of the Complete SE Vascular Stent System.

E. Animal Studies

The Complete SE Vascular Stent System was subjected to acute and chronic animal studies. The intent of the studies was to demonstrate acceptable functional performance of the subject devices in an *in vivo* setting and to ensure that the devices do not cause untoward hemodynamic vascular or other biological (e.g. thrombotic events) responses.

These studies include three 28-day GLP studies, one 180-day GLP study and two acute non-GLP studies. The four Chronic GLP studies were conducted in accordance with 21 CFR §58 Good Laboratory Practices (GLP). These six studies evaluated the safety and overall device performance.

In combination with the biocompatibility and clinical testing performed, the six preclinical studies demonstrate safety of the device by acceptable functional performance in an *in vivo* setting, and ensure that the devices do not cause untoward hemodynamic, vascular or other biological (e.g. thrombotic events) responses.

Table 5: Summary of Animal Testing

Study Name	# of Animals and # of Stents	Follow-up Duration	Relevant Findings
A GLP Study to Evaluate the Safety and Efficacy of the Iliac Self-Expanding Stent in a Porcine Peripheral Artery Model	Animals: 8 swine Test units: 11 Control units: 8	28 days ± 2 days post-implant	This study demonstrated that the Medtronic Iliac Self-Expanding (Bridge SE) stents in healthy porcine peripheral arteries over 28 days had acceptable subjective and morphometric outcomes when compared to the control stent.
A GLP Study to Evaluate the Long Term Safety and Efficacy of the Medtronic Self-Expanding Stent in a Porcine Peripheral Artery Model	Animals: 6 swine Test units: 6 Control units: 6	180 days ± 2 days post-implant	This study demonstrated that the Medtronic Self-Expanding Stent had acute and chronic performance equivalent to the control stent in healthy porcine peripheral arteries over 180-days.
Evaluation of the Bridge SE Nitinol Stent with Gold Markers in a Swine Model (GLP Study)	Animals: 10 swine Test units: 10 Control units: 10 (n=6, Medtronic Bridge SE without gold markers; n= 4, Cook Zilver)	28 days ± 2 days post-implant	This study demonstrated acceptable performance of the Medtronic SE Nitinol Peripheral Stent with Markers throughout all phases of the experimental study. The test article exhibited excellent radiopacity and the gold end markers substantially enhanced radiopacity of the device in comparison with the Medtronic Bridge SE Stent without gold markers and provided comparable radiopacity to the competitive stent. Chronic results showed the test article did not induce excessive vascular changes when compared to the control units.
Evaluation of the Medtronic Vascular Strider (Complete SE) Self Expanding Stent System in a Porcine Model ~A 28-day Safety Study~ (GLP Study)	Animals: 8 swine Test units: 8 Control units: 8 (n=4, Medtronic Aurora; n= 4, Cordis SMART)	28 days ± 2 days post-implant	This study demonstrated that acute performance of the Medtronic Vascular Strider stent was similar to the control articles and rated 'average' or better. IVUS evaluation of percent restenosis showed similar percent stenosis and there were no significant differences in the histomorphometric characteristics between test and control articles. Inflammation, injury scores and vessel healing parameters were minimal for all groups. SEM analysis showed no topographic anomalies, with well defined markers and no inflammatory cell response.
An Acute Performance Evaluation of the Complete SE Stent and Delivery System in a Swine Model	Animals: 2 swine Test units: 18 Control units: 6 (n=2, Medtronic Aurora; n= 2, Cordis SMART, n=1 Guidant Absolute, n=1	Acute	This study was an acute performance evaluation to semiquantitatively assess key performance characteristics. The ratings were acceptable compared to the competitive control stent systems in healthy porcine peripheral arteries.

Study Name	# of Animals and # of Stents	Follow-up Duration	Relevant Findings
	Edwards LifeStent)		
An Acute Performance Evaluation of the Complete SE in a Swine model	Animals: 2 swine Test Units: 3 Control units: 0	Acute	This study demonstrated the 120mm and 150mm Medtronic Vascular Complete SE Stent Systems had acceptable acute performance in healthy porcine iliac arteries. FDA requested this information in their Conditional Approval letter on Aug 2, 2007 for G070114, specifically regarding the *in vivo* performance of 120mm length stent. Medtronic Vascular submitted this as an IDE supplement G070114/S002 on October 15, 2007.

Animal Studies were conducted using both the Bridge SE and Complete SE Vascular Stents. Bench testing demonstrated that the two stents have comparable characteristics and performance. Although some of the animal studies were conducted using the Bridge SE Stent, FDA has determined that the data support the approval of the Complete SE Stent.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the Complete SE Vascular Stent System for improving luminal diameter in symptomatic patients with *de novo* and/or restenotic lesions or occlusions of the superficial femoral artery (SFA) or proximal popliteal artery (PPA) with reference diameters ranging from 4 mm to 7 mm and lesion lengths up to 140 mm, in the US, Germany, and Belgium under IDE # G080143. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between November 21,2008 and July 22, 2010. The database for this PMA reflected data collected through September 27, 2011 and included 196 patients. There were 28 investigational sites.

The study was a prospective, multi-center, non- randomized, un-blinded single arm clinical study comparing percutaneous transluminal angioplasty (PTA) and primary stenting with the Complete SE Stent System to performance goals of PTA alone in the treatment of atherosclerotic lesions of the native superficial femoral artery (SFA) or the superficial femoral and proximal popliteal arteries. The safety performance goal was derived from literature and the effectiveness performance goal was based on an aggregate of published trial data as described by VIVA physicians Inc. (VPI). This study was conducted at 28 global (23 US) investigational sites. A total of 196 subjects were enrolled. Eligible subjects either had stenotic, restenotic (non-stented) or occluded lesions. The reference vessel diameter of the treated subjects was to be 4.0 - 7.0 mm and the lesion length from 4-14 cm. Subjects with Rutherford/Becker Clinical Categories of 2-4 were included in the study. Subject follow-up occurred at 30 days, 6 months, and 12 months, and will continue with annual follow-up for up to 3 years.

The primary study endpoints were as follows:

- The primary safety endpoint for the Complete SE SFA/PPA study is Major Adverse Event (MAE) rate at 12 months. MAE is defined as device or procedure-related death (or any death occurring post-procedure through Day 30), target limb loss and target lesion or target vessel revascularization.

- The primary effectiveness endpoint for the Complete SE SFA/PPA study is the primary patency rate at 12 months. Primary patency defined as uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by peak systolic velocity ratio ≥2.0 as assessed by duplex ultrasound (DUS).

Study success was declared only if both primary endpoints (safety and effectiveness) met their performance goals. For the primary safety endpoint, the null hypothesis was rejected if the upper limit of the one-sided 97.5% confidence interval on the 12 months MAE rate was less than 40%. The one-sided 97.5% confidence intervals were calculated using the exact binomial test method. For the primary effectiveness endpoint, the null hypothesis was rejected if the lower limit of the one-sided 97.5% confidence interval on the 12 months patency rate exceeded 66%.

The Complete SE SFA Study was monitored by independent contract monitors. Independent duplex ultrasound and angiographic core laboratories reviewed and analyzed key study variables. An independent Data Safety Monitoring Board (DSMB) was used to review study data on an ongoing basis and identify any potential safety trends. Adjudication of major adverse events was conducted by an independent Clinical Events Committee (CEC).

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the Complete SE SFA/PPA study was limited to patients who met the following inclusion/exclusion criteria:

Table 6: Inclusion/Exclusion Criteria

Inclusion	Exclusion
• The lesion length is >= 4.0 cm and <= 14.0 cm (visual estimate)	• The subject has non-target lesions, other than iliac lesions, that require intervention during the index procedure, or within 30 days before or after the index procedure
• The total lesion length is >= 40 mm and <= 140 mm (visual estimate). If two lesions will be treated, the combined lesion length must be <=140mm, the lesions must be in the same limb, and the treatment must not require more than 150 mm combined total stent length.	• The subject has non-target lesions, other than those defined in section 3.3.1 (i.e., iliac non-target lesions treated prior to enrollment with optimal results) that require intervention during the index procedure, or within 30 days before or after the index procedure

Inclusion	Exclusion
• The total lesion length is >= 40 mm and <= 140 mm (visual estimate). If two lesions will be treated, the combined lesion length is <=140mm and treatment does not require more than 150mm total stent length	• The subject has non-target lesions, other than those described in Section 3.3 of the protocol, that require intervention during the index procedure, or within 30 days before or after the index procedure
• The subject is symptomatic with Rutherford classification 2-4 (as assessed by the Walking Impairment Questionnaire [WIQ])	• The subject has a known allergy or contraindication to any component of the stent system, aspirin, heparin, or a sensitivity to contrast media which cannot be adequately pre-medicated
• The subject is symptomatic with Rutherford classification 2-4.	• The subject has a known allergy or contraindication to any component of the stent system, aspirin, heparin, or sensitivity to contrast media which cannot be adequately pre-medicated
• The subject has an ABI <0.90 or, if ABI not feasible, a TBI <0.80	• The subject has a known platelet count <80,000 cells/mm³ or >700,000 cells/mm³ within 7 days prior to the index procedure
• The subject has an ABI <=0.90 or, if ABI not feasible due to medical condition, such as non-compressible vessels, a TBI <=0.80	
• The subject has an ABI <=0.90 or, if ABI not feasible due to medical condition, such as non-compressible vessels, a TBI <=0.80.	
• The subject has adequate distal run-off to the ankle in the target limb (defined as having at least one patent calf vessel <50% stenosed)	

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 ± 5 days and at 6 months, 12, 24 and 36 months ± 30 days postoperatively.

The pre-operative, procedural, post-operative and follow-up evaluations are listed in the table below. Adverse events and complications were recorded at all visits.

The key time-points are shown below in the table summarizing safety and effectiveness.

Table 7: Required Study Procedures and Evaluations

Requirement	Pre-Procedure	During Procedure	Post-Procedure/ Pre-Discharge	30 days ±5 Days*	6 months ±30 Days**	12 months ± 30 Days**	24 Months ± 30 Days**	36 Months ± 30 Days**
Informed Consent	X							
Office Visit	X			X	X	X	X	X
CBC and platelet count	X		X					
Serum creatinine	X		X					
Pregnancy test, if applicable (serum or urine)	X							
ACT	X	As per hospital standard						
ABI/TBI	X			X	X	X		
Major Adverse Events Assessment			X	X	X	X	X	X
Rutherford Classification and Walking Impairment Questionnaire (WIQ)	X			X	X	X		
Angiogram	X	X	As clinically indicated	As clinically indicated	As clinically indicated	As clinically indicated	As clinically indicated	As clinically indicated
Duplex ultrasound (DUS)					X	X		
Flat plate x-ray, AP & lateral						X	X	X

* Window = 25-35 days post-procedure
** Window = Count ± 30 days from each 6 mo, 12 mo, 24 mo, or 36 mo anniversary date

3. Clinical Endpoints

With regard to success/failure criteria, the compare the primary clinical endpoints to the pre-established safety and effectiveness performance goals of 40% for safety and 66% for effectiveness (defined below).

Safety

The primary safety endpoint was defined as device or procedure-related death (or any death occurring post-procedure through Day 30), target limb loss and target lesion or target vessel revascularization occurring through 12 months.

Secondary safety endpoints included:

- Major Adverse Event (MAE) rate at 30 days and 6, 24 and 36 months. MAE is defined as device or procedure-related death (or any death occurring post-procedure through Day 30), target limb loss and target lesion or target vessel revascularization.
- Stent integrity assessed by x-ray evaluation at 1, 2, and 3 year follow-up

Effectiveness

The primary effectiveness endpoint for the Complete SE SFA/PPA study is the primary patency rate at 12 months. Primary patency defined as uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by peak systolic velocity ratio ≥2.0 as assessed by duplex ultrasound (DUS).

Secondary effectiveness endpoints included:

- Acute success (device, lesion, and procedure)
- Change in Quality of Life, defined as:
    - Improvement in Rutherford class by ≥ 1 category at 12 months from pre-procedure; or
    - Increase in ankle/brachial index (ABI) or toe/brachial index (TBI) ≥ 0.15 at 12 months from pre-procedure; or
    - Decline in Rutherford class by ≥ 1 category at 30 days when compared to pre-procedure.
- Assisted primary patency at 12 months. Assisted primary patency is defined as vessel patency resulting from any procedure performed in the treated segment to restore blood flow after restenosis. Secondary patency at 12 months. Secondary patency is defined as vessel patency resulting from any procedure that restores patency.
- Clinically-driven TLR at 12 months

B. Accountability of PMA Cohort

At the time of database lock, of the 196 subjects enrolled in the PMA study, 95% (n=187) of subjects were eligible for the 12-month endpoint.

Table 8: Subject Follow-Up Compliance

Subject Compliance	N = 196
30-Day Follow-up	
Eligible Subjects[a]	196
Follow-up Visit within Window[b]	161
Follow-up Compliance (%)[c]	82.1
6-Month Follow-up	
Eligible Subjects[a]	192
Follow-up Visit within Window[b]	163
Follow-up Compliance (%)[c]	84.9
12-Month Follow-up	
Eligible Subjects[a]	187
Follow-up Visit within Window[b]	166
Follow-up Compliance (%)[c]	88.8

[a] Eligible subjects are all subjects who are enrolled and 1) had a follow-up at or after the lower limit window, or 2) were enrolled and have reached the upper limit of the window, or 3) were lost to follow-up before the upper limit of the window
[b] Within window visits are defined as: 30 days ± 5 days, 6 months ± 30 days, 12 months ± 30 days, 24 months ± 30 days, 36 months ± 30 days
[c] Percentage based on number of subjects who had follow-up visit within window divided by number of eligible subjects
N = Intent-To-Treat Population
Note: Site Reported Table

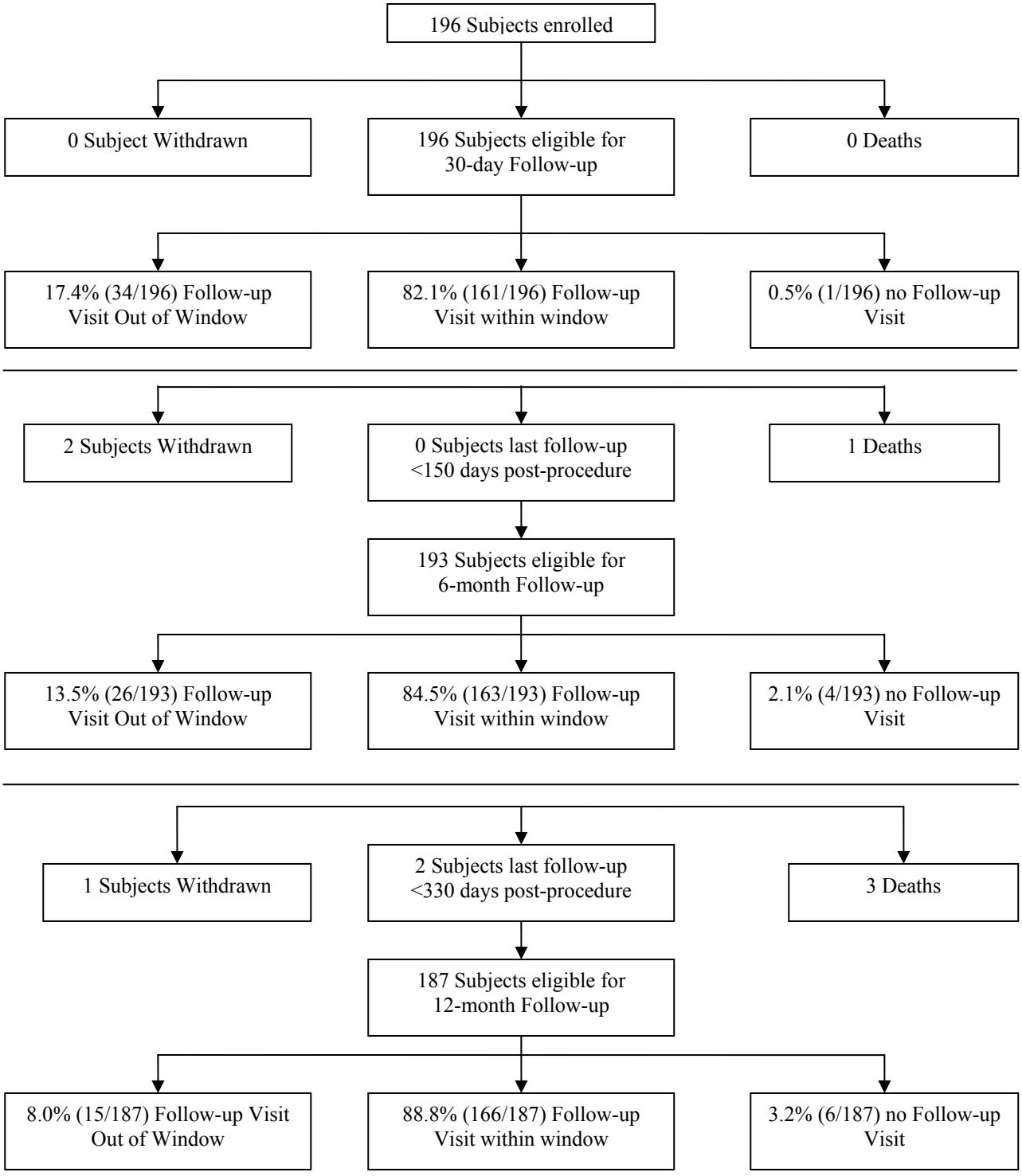


Figure 3: Subject Accountability

C. Study Population Demographics and Baseline Parameters

The Complete SE SFA/PPA clinical study included 196 subjects with symptomatic ischemic PAD. The Intent-to-Treat population results indicate the mean age for subjects was 69 years, of which 63.3% (124/196) were male, 45.4% (89/196) had diabetes mellitus, 62.8% (123/196) had a history of coronary artery disease and 53.1% (103/194) had previous peripheral vascular disease other than SFA and PPA disease. The demographics of the study population are typical for an interventional peripheral vascular study performed in the US.

Table 9: Subject Demographics, Medical History and Risk Factors

Subject Demographic, Medical History and Risk Factors[a]	N = 196
Age (year)	
n	196
Mean ± SD	68.7 ± 10.5
Median	68.0
Min, Max	40, 93
Sex % (m/n)	
Male	63.3 (124/196)
Medical History and Risk Factors % (m/n)	
Diabetes Mellitus	45.4 (89/196)
Type I	1.5 (3/196)
Type II	43.9 (86/196)
Dyslipidemia	79.6 (156/196)
Hypertension	90.3 (177/196)
History of Tobacco Use	79.6 (156/196)
Former	52.6 (103/196)
Current	27.0 (53/196)
History of Coronary Artery Disease	62.8 (123/196)
History of COPD	21.4 (42/196)
Previous MI	26.2 (49/187)
Previous Peripheral Vascular Disease (other than SFA and PPA)	53.1 (103/194)
History of CVA	14.3 (28/196)
Previous PTA/Stenting to Target Limb	18.4 (36/196)
Previous Aorta/Peripheral Bypass to Target Limb	1.5 (3/196)
History of GI/GU Bleed	5.6 (11/196)

[a] Based on number of subjects with available data
N = Intent-To-Treat Population
Note: Site Reported Table

Of the 196 subjects treated as part of the Complete SE SFA/PPA Study, 49.7% of the subjects had distal SFA/PPA lesions, 34.3% of subjects had mid-SFA lesions and 16.0% had proximal SFA lesions.

Table 10: Lesion Characteristics

Angiographic Quantitative Analysis [a]	Lesions [b] = 213
Lesion Location (%)	
SFA Ostial	**2.3 (5/213)**
SFA Proximal	**13.6 (29/213)**
SFA Mid	**34.4 (73/213)**
SFA Distal	**45.5 (97/213)**
Proximal Popliteal Artery	**4.2 (9/213)**
Reference vessel diameter (mm)	
Mean ± SD (n)	**4.8±0.9 (209)**
Minimum, maximum	**2.2, 7.6**
Lesion length (total) (mm)	
Mean ± SD (n)	**60.7±37.6 (209)**
Minimum, maximum	**5, 228**
Lesion pre-procedure % stenosis	
Mean ± SD (n)	**79.7±16.1 (209)**
Minimum, maximum	**51.1, 100**
Lesion post-procedure % stenosis	
Mean ± SD (n)	**16.9±9.3 (211)**
Minimum, maximum	**1.4, 40.5**
Lesions treated with 1 study stent	**203**
Lesions treated with 2 study stents	**11**
Lesion Characteristic	**% (m/n)**
Eccentric	**31 (65/210)**
Ulceration	**17.6 (37/210)**
Calcification	**91 (191/210)**
None/Mild	**9 (19/210)**
Moderate	**34.8 (73/210)**
Severe	**56.2 (118/210)**
Thrombus	**0 (0/210)**
Total Occlusion	**29.9 (60/201)**
Dissection Grade	
0 (no dissection)	**97.2 (205/211)**
A	**0 (0/211)**
B	**1.9 (4/211)**
C	**0.5 (1/211)**
D	**0.5 (1/211)**
E	**0 (0/211)**
F	**0 (0/211)**

[a]Based on the number of lesions with available data.
[b]Lesions as Angiographic Core Laboratory Reported.

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the 196 subjects for the 12 month evaluation. The key safety outcomes for this study are presented below in tables 11 to 14. Adverse effects are reported in tables 12.

The primary safety endpoint is major adverse event (MAE) rate at 12 months. MAE is defined as device or procedure related death (or any death occurring post procedure through 30 days), target limb loss and target lesion or target vessel revascularization. The overall MAE rate at 12 months was 11.0% (21/191). The upper bound of the exact one-sided confidence interval (16.3%) was lower than the pre-specified performance goal of 40% indicating the study met its primary safety endpoint.

Table 11: Primary Safety Endpoint

	N = 196 Lesions[b] = 213	
Primary Safety Endpoint	**% (m/n)[a]**	**Exact One-sided Upper 97.5% CI**
MAE at 12 Months	11.0 (21/191)	16.3%
Death through 30 Days	0.0 (0/191)	1.9%
Death (Device and/or Procedure Related)	0.0 (0/191)	1.9%
Device Related	0.0 (0/191)	1.9%
Procedure Related	0.0 (0/191)	1.9%
Target Limb Loss	0.5 (1/191)	2.9%
TLR	9.4 (18/191)	14.5%
PTA	8.9 (17/191)	13.9%
Bypass Graft	0.5 (1/191)	2.9%
TVR	11.0 (21/191)	16.3%
PTA	10.5 (20/191)	15.7%
Bypass Graft	0.5 (1/191)	2.9%

[a]Percentage based on number of evaluable subjects for MAE. Subjects will be considered unevaluable for MAE at 12 months if a)the subject withdrew before 330 days without having MAE events or b) the subject was lost to follow-up before 330 days without having MAE events and had no contact thereafter or c) any device and/or procedure-unrelated death occurred after 30 days and before 330 days without having MAE events

[b] Lesions as reported by the Angiographic Core Laboratory

Adverse effects that occurred in the PMA clinical study:

There were no MAEs in-hospital. Eighteen of the 21 subjects having revascularizations had them in the target lesion. One of the TLRs involved a bypass graft and the remaining TLRs were percutaneous interventions.

Table 12: Major Adverse Events to 12 Months
(In Hospital and Out-of-Hospital)

	N = 196
Major Adverse Events	**% (m/n)**
In Hospital	
MAE	0.0% (0/196)
Death through 30 Days	0.0% (0/196)
Death (Device and/or Procedure Related)	0.0% (0/196)
Device Related	0.0% (0/196)
Procedure Related	0.0% (0/196)
Target Limb Loss	0.0% (0/196)
TLR	0.0% (0/196)
PTA	0.0% (0/196)
Bypass Graft	0.0% (0/196)
TVR	0.0% (0/196)
PTA	0.0% (0/196)
Bypass Graft	0.0% (0/196)
Out of Hospital	
MAE	10.7% (21/196)
Death through 30 Days	0.0% (0/196)
Death (Device and/or Procedure Related)	0.0% (0/196)
Device Related	0.0% (0/196)
Procedure Related	0.0% (0/196)
Target Limb Loss	0.5% (1/196)
TLR	9.2% (18/196)
PTA	8.7% (17/196)
Bypass Graft	0.5% (1/196)
TVR	10.7% (21/196)
PTA	10.2% (20/196)
Bypass Graft	0.5% (1/196)
Cumulative to 12 Months	
MAE	11.0% (21/191)
Death through 30 Days	0.0% (0/191)
Death (Device and/or Procedure Related)	0.0% (0/191)
Device Related	0.0% (0/191)
Procedure Related	0.0% (0/191)
Target Limb Loss	0.5% (1/191)
TLR	9.4% (18/191)
PTA	8.9% (17/191)
Bypass Graft	0.5% (1/191)

	N = 196
Major Adverse Events	**% (m/n)**
TVR	11.0% (21/191)
PTA	10.5% (20/191)
Bypass Graft	0.5% (1/191)

[a] Percentage based on number of evaluable subject for MAE
N = Intent-To-Treat Population
Note: CEC Reported Table

An adverse event (AE) is defined as any untoward medical occurrence in a subject. Summary data on system organ class for AEs are summarized below. The most common events were related to vascular disorders reported at 44.9%.

Table 13: Subjects with Adverse Events through 12-Month Visit

	N = 196 Total Adverse Events = 670 Subjects with at Least one Adverse Event = 156
System Organ Class	**Number of Subjects % (m/n)[a]**
Blood and Lymphatic System Disorders	7.1 (14/196)
Cardiac Disorders	19.4 (38/196)
Congenital, Familial and Genetic Disorders	0.5 (1/196)
Ear and Labyrinth Disorders	1.0 (2/196)
Endocrine Disorders	1.0 (2/196)
Eye Disorders	1.0 (2/196)
Gastrointestinal Disorders	18.4 (36/196)
General Disorders and Administration Site Conditions	20.4 (40/196)
Hepatobiliary Disorders	2.0 (4/196)
Infections and Infestations	15.3 (30/196)
Injury, Poisoning and Procedural Complications	18.4 (36/196)
Investigations	4.1 (8/196)
Metabolism and Nutrition Disorders	6.1 (12/196)
Musculoskeletal and Connective Tissue Disorders	24.0 (47/196)
Neoplasms Benign, Malignant and Unspecified (Incl. Cysts and Polyps)	3.6 (7/196)
Nervous System Disorders	15.3 (30/196)
Psychiatric Disorders	4.1 (8/196)
Renal and Urinary Disorders	8.2 (16/196)
Reproductive System and Breast Disorders	2.0 (4/196)
Respiratory, Thoracic and Mediastinal Disorders	9.7 (19/196)
Skin and Subcutaneous Tissue Disorders	6.6 (13/196)

	N = 196 Total Adverse Events = 670 Subjects with at Least one Adverse Event = 156
System Organ Class	**Number of Subjects % (m/n)[a]**
Surgical and Medical Procedures	3.6 (7/196)
Vascular Disorders	44.9 (88/196)

[a] Percentage based on number of subjects in ITT population
N = Intent-To-Treat Population
Note: Site Reported Table

Table 14: Cumulative Survival Distribution Function Estimate Over 365 Days Period for Subjects with MAE

	Time after initial procedure (days)												
MAE	**0**	**30**	**60**	**90**	**120**	**150**	**180**	**210**	**240**	**270**	**300**	**330**	**365**
# Entered	196	196	195	194	193	188	188	183	178	172	171	170	167
# Censored	0	0	0	0	3	0	2	1	2	0	0	0	167
# Events (CEC adjudicated)	0	1	1	1	2	0	3	4	4	1	1	3	0
% Cumulative Incidence	0.0%	0.5%	1.0%	1.5%	2.6%	2.6%	4.1%	6.2%	8.4%	8.9%	9.4%	11.0%	11.0%
Standard Error	0.0%	0.5%	0.7%	0.9%	1.1%	1.1%	1.4%	1.7%	2.0%	2.1%	2.1%	2.3%	2.3%

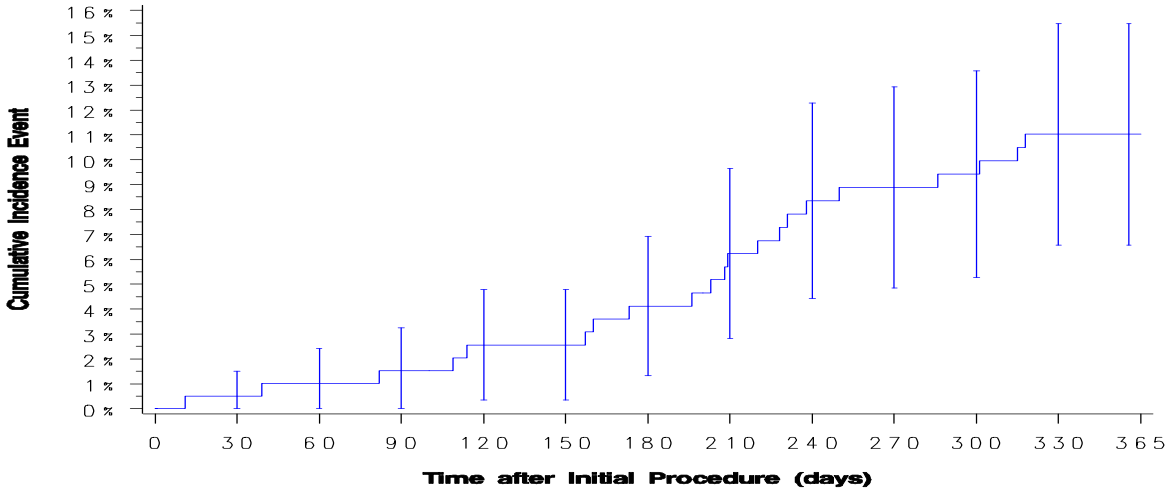


Figure 4: Cumulative Survival Distribution Function Estimate Over 365 Days Period for Subjects with MAE

Secondary Safety Endpoint Analysis

There were nine (9) Core Lab reported fractures at 1-year.

Table 15: Secondary Safety Endpoints

Secondary Endpoint	% (m/n)	Exact Two-sided 95% CI
Stent integrity at 12 Months	95.8 (181/190)	(91.8%, 98.2%)

In an effort to provide FDA an assessment of the fractures, Medtronic and the Core Lab conducted a detailed fracture analysis which was beyond the scope of the original fracture adjudication method. FDA has reviewed this detailed fracture analysis described below and believes that it accurately represents the findings regarding stent integrity.

As part of the additional analysis, Medtronic assessed the presence of calcification/atheroma, fracture location, oversizing, stretching, overlap/non-overlap, and occurrence of target lesion revascularization (TLR) for all reported events. Medtronic obtained images for all patients at the follow-up time points (i.e., 1 year, 2 year and 3 year) and evaluated the clinical images of each patient at multiple time-points and different views. Medtronic re-produced the fractures using bench testing/models and evaluated the safety factors utilizing Finite Element Analysis (FEA).

Of the 9 Core Lab reported fractures reported at 1 year, Medtronic has determined that 8 of the fractures were in fact cases of crown deflections resulting in stent conformation to calcium, which could be attributed to the interaction of the open cell design of the Complete SE stent and the lesion. This finding is supported by the time series of images which demonstrate the challenge of visual analysis of a fracture in a single plane. Figure 5, for example, demonstrates a suspected fracture that appeared at 12 months but diminished at 2 and 3 years. The other reported fractures were determined to not be fractures utilizing a similar methodology. In addition, one (1) fracture that was initially Core Lab reported was assessed to be a device other than a Medtronic Complete SE stent. Therefore, at 1 year, it was determined that there were zero fractures.

Table 16: Fractures After Additional Analysis

Fracture Reported by Core Lab at 1 year	*9*
Final Number of Suspected Fractures as Determined by Additional Analysis	*0*
Total Number of Fractures at 1 Year	***0***

* Test data on file at Medtronic

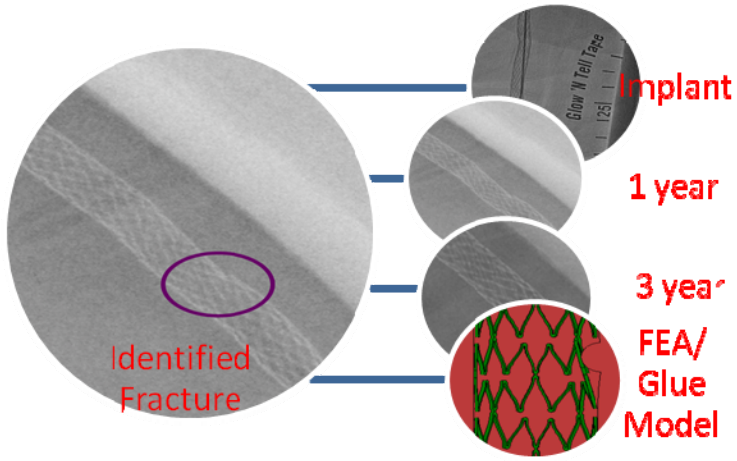


Figure 5: Reported Fracture Dissipates Over Time

2. Effectiveness Results

The analysis of effectiveness was based on the 175 evaluable at the 12-month time point.

The primary effectiveness endpoint was primary patency at 12 months. Primary patency is defined as uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by peak systolic velocity ratio ≥2.0 as assessed by duplex ultrasound. The primary patency rate at 12 months was 72.6% (128/175). The lower bound of the 97.5% confidence interval for primary patency at 12 months was 65.9%.

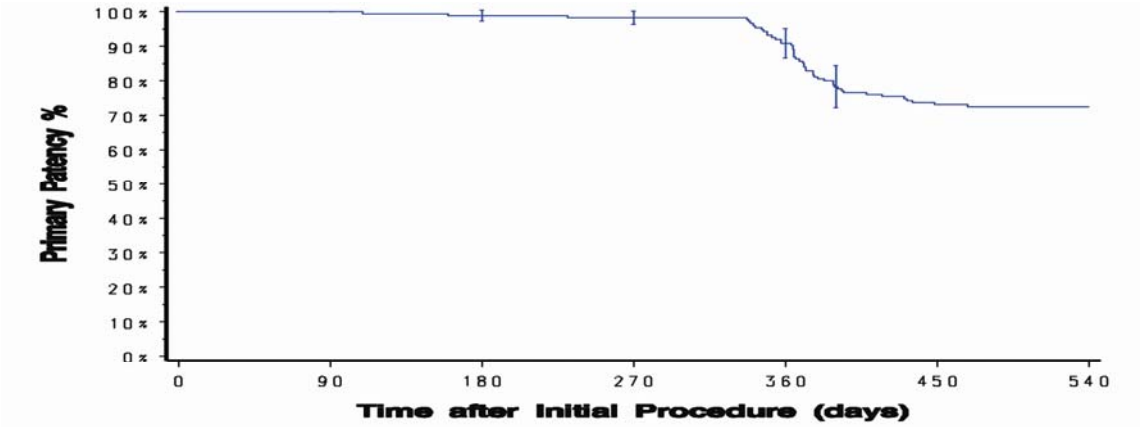
In further consideration of the overall device performance as well as to allow the application of a more modem study design, a secondary analysis of the data was also performed. The secondary analysis applied a modified VIVA effectiveness criterion which uses a higher PSV ratio. Using these modified criteria of a PSV ratio < *2.4*, the mean primary patency rate as a measure of primary effectiveness at 12 months was 72.6% with a lower *97.5%* CI of 65.3%.

Key effectiveness outcomes are presented in Table 17 through Table 19 and Figure 6 below.

Table 17: Primary Effectiveness Endpoint (Protocol Specified)

Primary Effectiveness Endpoints	% (m/n)[a]	Exact One-sided Lower 97.5% CI
Primary Patency [b] Rate at 12 Months	72.6 (127/175)	65.3%

[a] Percentage based on number of subjects who had available duplex data (for subjects with more than one duplex scan analysis the worst case is counted)
[b] Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥50% as documented by DUS peak systolic velocity ratio ≥ 2.0



	Time after initial procedure (days)					
Patency	0 - 90	91 - 180	181 - 270	271 - 360	361 - 390	>=391
# Risk[1]	175	175	173	172	159	137
# Censored[2]	0	0	0	0	0	127
# Events	0	2	1	13	22	10
Kaplan-Meier Estimate[3]	100.0%	98.9%	98.3%	90.9%	78.3%	72.5%
Standard Error	0.0%	0.8%	1.0%	2.2%	3.1%	3.4%

[1]Number of subjects at risk at the beginning of an interval.
[2]Subjects are censored because their last follow-up has not reached the end of the time interval. Censored subjects will include those who withdraw, are lost to follow-up or die.
[3]Kaplan-Meier Estimate and Standard Error were calculated at the end of a time interval.

Figure 6: Kaplan-Meier Estimates of Primary Patency Over Time

The primary patency rate for this study using the PSVR ≥ 2.4 is 74.9% (131/175) with an exact one-sided 97.5% lower confidence interval of 67.8%.

Table 18: Primary Patency with a PSVR Cut-off of ≥ 2.4

Primary Effectiveness Endpoints	% (m/n) [a]	Exact One-sided Lower 97.5% CI
Primary Patency Rate[b] at 12 Months (cut-off of PSVR 2.4)	74.9 (131/175)	67.8%

[a] Percentage based on number of subjects who had available duplex data (for subjects with more than one duplex scan analysis the worst case is counted)
[b]Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis >=50% as documented by DUS peak systolic velocity ratio ≥2.4

Table 19 presents a lesion length tercile analysis based on Complete SE SFA/PPA Study outcomes and analyzed using a PSV ratio threshold of 2.0 and clinically-driven TVR as well as using modified VIVA criteria using a higher PSV ratio (2.4*)*.

Table 19: Primary Patency to 12 Months as a Function of Lesion Length

	Total N = 196 Total Lesions[a] = 213 Lesion Length Terciles		
	Lower (N = 65 Patients N= 71 Lesions)	**Mid (N = 65 Patients N= 74 Lesions)**	**Upper (N = 66 Patients N= 68 Lesions)**
Pre-Procedure Lesion Length (mm)			
n	71	73	65
Mean ± SD	27.31 ± 10.13	53.21 ± 13.75	105.65 ± 30.15
Median	28.0	55.0	99.1
Min, Max	5.0, 40.3	11.4, 73.4	37.3, 228.0
Primary Effectiveness Endpoint			
Primary Patency (PSVR ≥2.0)[b,c] Rate at 12 Months	83.6% (46/55)	68.9% (42/61)	66.1% (39/59)
Primary Patency (PSVR ≥ 2.4)[b,c] Rate at 12 Months	83.6% (46/55)	70.5% (43/61)	71.2% (42/59)

[a]Lesions as reported by the Angiographic Core Laboratory. In subjects with more than one lesion the longest lesion was used for categorizing them into lesion length terciles.
[b]Percentage based on number of subjects who had available duplex data (for subjects with more than one duplex scan analysis the worst case is counted)
[c]Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis >=50% as documented by DUS peak systolic velocity ratio ≥2.0 or ≥ 2.4
N = Intent-To-Treat Population
Note: Site, CEC, Duplex and Angiographic Core Laboratory Reported Table

Secondary Effectiveness Endpoint Analysis

The secondary effectiveness endpoints are summarized in the tables below:

Table 20: Secondary Effectiveness Endpoints

Secondary Effectiveness Endpoints	**% (m/n)**	**Exact Two-sided 95% CI**
MAE at 30 Days	0.5 (1/196)	(0.0%, 2.8%)
MAE at 6 Months	4.1 (8/194)	(1.8%, 8.0%)
Device Success	90.0 (189/210)	(85.1%, 93.7%)

Secondary Effectiveness Endpoints	% (m/n)	Exact Two-sided 95% CI
Lesion Success	90.0 (190/211)	(85.2%, 93.7%)
Procedure Success	89.1 (172/193)	(83.8%, 93.1%)
Assisted Primary Patency Rate at 12 Months	78.3 (137/175)	(71.4%, 84.2%)
Secondary Patency Rate at 12 Months	78.9 (138/175)	(72.1%, 84.7%)
Change in Quality of Life:		
Improvement in Rutherford Class by >= 1 Category at 12 Months	90.9 (160/176)	(85.7%, 94.7%)
Increase in ABI or TBI >= 0.15 at 12 Months	64.5 (107/166)	(56.7%, 71.7%)
Decline in Rutherford Class >= 1 Category at 30 Days	89.7 (174/194)	(84.5%, 93.6%)
Clinically-driven TLR at 12 Months	8.4 (16/191)	(4.9%, 13.2)

There were 3 measures of Quality of Life observed at 12 months: improvement in Rutherford Class by ≥1 category, increase in ABI/TBI of ≥0.15, and decline in Rutherford Class ≥1.

3. Subgroup Analyses

a. Applicability to Pediatric Populations

Peripheral artery disease is not typically found in pediatric populations excepting rare homozygous lipid disorders. Accordingly, the safety and effectiveness of the Complete SE in pediatric populations was not studied in the Complete SE SFA/PPA study.

b. Gender Sub-group Analysis

A breakdown of primary and secondary endpoints through 12 months by gender is presented below. The representation of females in the study (36%) is similar to that of the general population with PAD and other interventional studies. The MAE rate at 12 months was 9.9% for males and 12.9% for females. The primary patency rate at 12 months was 74.1% for males and 69.8% for females. As shown in the tables below, relatively small differences in outcomes were observed between the sexes in this study and the results are considered comparable.

Table 20: Primary Endpoints through 12 Months by Gender

	N = 196 Lesions[d] = 213	
Primary Safety Endpoint	**Male % (m/n)[a]**	**Female % (m/n)[a]**
MAE at 12 Months	9.9 (12/121)	12.9 (9/70)
Death through 30 Days	0.0 (0/121)	0.0 (0/70)
Death (Device and/or Procedure Related)	0.0 (0/121)	0.0 (0/70)
Device Related	0.0 (0/121)	0.0 (0/70)
Procedure Related	0.0 (0/121)	0.0 (0/70)
Target Limb Loss	0.8 (1/121)	0.0 (0/70)
TLR	9.9 (12/121)	8.6 (6/70)

	N = 196 Lesions[d] = 213	
Primary Safety Endpoint	**Male % (m/n)[a]**	**Female % (m/n)[a]**
PTA	9.9 (12/121)	7.1 (5/70)
Bypass Graft	0.0 (0/121)	1.4 (1/70)
TVR	9.9 (12/121)	12.9 (9/70)
PTA	9.9 (12/121)	11.4 (8/70)
Bypass Graft	0.0 (0/121)	1.4 (1/70)
Primary Effectiveness Endpoint	**Male % (m/n)[b]**	**Female % (m/n)[b]**
Primary Patency[c] Rate at 12 Months	74.1 (83/112)	69.8 (44/63)

Table 21: Secondary Endpoints through 12 Months by Gender

Secondary Endpoints	Male % (m/n)	Female % (m/n)
MAE at 30 Days	0.8 (1/124)	0.0 (0/72)
MAE at 6 Months	3.3 (4/122)	5.6 (4/72)
Device Success	86.8 (112/129)	95.1 (77/81)
Lesion Success	86.9 (113/130)	95.1 (77/81)
Procedure Success	86.0 (104/121)	94.4 (68/72)
Assisted Primary Patency Rate at 12 Months	82.1 (92/112)	71.4 (45/63)
Secondary Patency Rate at 12 Months	83.0 (93/112)	71.4 (45/63)
Change in Quality of Life:		
Improvement in Rutherford Class by >= 1 Category at 12 Months	91.1 (102/112)	90.6 (58/64)
Increase in ABI or TBI >= 0.15 at 12 Months	66.0 (68/103)	61.9 (39/63)
Decline in Rutherford Class >= 1 Category at 30 Days	88.6 (109/123)	91.5 (65/71)
Stent integrity at 12 Months	95.8 (115/120)	95.7 (66/69)
Clinically-driven TLR at 12 months	8.3 (10/21)	8.6 (6/70)

N = Intent-To-Treat Population
Note: Site, CEC, Duplex and Angiographic Core Laboratory Reported Table

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 28 Principal Investigators and 95 Sub-Investigators. None of the clinical investigators had

disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of Section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory Systems Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in a clinical study conducted to support PMA approval as described above.

The primary safety objective was the rate of Major Adverse Events at 12 months. MAE was defined as device or procedure related death (or any death occurring post-procedure through 30 days), target limb loss, and target lesion or target vessel revascularization. Study success of the Complete® Self-Expanding Stent System was based on a 12-Month MAE rate less than 40%. The 12-Month MAE rate of 11.0% (21/191; 95% CI, 6.9%, 16.3%) with upper 97.5% CI of 16.3% was lower than the pre-specified performance goal, thus indicating the study met its primary safety endpoint.

B. Effectiveness Conclusions

The primary effectiveness objective was to observe primary patency at 12 months defined as *uninterrupted* patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by peak systolic velocity ratio (PSVR) ≥2.0 assessed by duplex ultrasound. The primary patency rate at 12 months was 72.6% (127/175; 95% CI, 65.3%, 79.0%). The lower bound of the 97.5% CI for primary patency at 12 months of 65.3% was slightly below the performance goal of 66%.

In further consideration of the overall device performance as well as to allow the application of a more modern study design, a secondary analysis of the data was also performed. The secondary analysis evaluated patency at a higher PSV ratio (2.4). Using this modified patency evaluation, a secondary analysis on the ITT population of primary patency revealed a rate of 74.9% (131/175; 95% CI, 67.8%, 81.1%) and lower bound of the 97.5% CI of 67.8% thereby meeting the VPI established goal of 66%.

C. Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The probable benefit of the

Complete SE Vascular Stent System of improving the patient symptoms and quality of life outweigh the probable risks associated with use of the device.

Additional factors that were considered in determining probable risks and benefits for Complete SE Stent System included:

- Patient follow-up was satisfactory and with limited missing data. Follow-up for the PMA was 12 months, with some patients followed out to 24 months but follow-up will continue for 3years to evaluate the longer term device performance, such as the duration of the benefit and long term adverse event rates.

- The pivotal study was a multi-center study conducted in the United States and other international sites. The results obtained should not differ from the post-market performance. Additional long-term data will be obtained.

- Most patients with the disease have symptoms only, but some patients may have more extensive disease involvement. The device treats the hemodynamic consequences of the disease to improve perfusion and function. The disease is chronic and affects the mobility of the patient and the quality of life. It is treatable but not curable.

- There are alternative treatments available, but this treatment is highly valued by patients and preferred to the alternatives because it improves their quality of life with lesser need for repeat procedures compared to a performance goal based upon angioplasty results without stenting.

- Patient risk is minimized by limiting use to operators who have the necessary training to use the device safely and effectively and by adherence to recommended periprocedural medication regimens.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for using the device for improving luminal diameter for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameters ranging from 4 mm to 7 mm and total lesion lengths up to 140 mm.

D. Overall Conclusions

The clinical and non-clinical data in this application provide a reasonable assurance that the device is safe and effective. While the pre-specified effectiveness endpoint was not met, the study results are similar to the results for other US marketed stents intended for use in patients with SFA and proximal popliteal artery lesions. Therefore, it is reasonable to conclude that the benefits of use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the labeling and Instructions for Use (IFU).

XIII. CDRH DECISION

CDRH issued an approval order on September 19, 2013. The final conditions of approval cited in the approval order are described below.

In addition to the general conditions outlined, the sponsor must conduct a post-approval study to evaluate the long-term safety and effectiveness of the Complete SE Vascular System in the pivotal study cohort through 3 years post implantation as outlined below.

1. *Complete SE SFA Long Term Study*: This study must be conducted per Protocol Revision D dated December 18, 2012 and Statistical Analysis Plan Revision 2.0 dated December 12, 2012 located in Amendment 5. This study will be a prospective, single-arm, multi-center continued follow-up of the Complete SE SFA pivotal study. All 172 remaining patients (24 patients exited due to death) of the 196 SE SFA pivotal study patients enrolled from 28 investigational sites, will be followed annually through 3 years post implantation.

   The primary endpoint is a composite of freedom from acute death, amputation, and TLR events assessed at 36 months. The primary endpoint will be compared to a performance goal of 35%. A minimum of 137 patients are required to provide >95% power to test the primary hypothesis.

   The secondary endpoints are (1) All-cause mortality (2) Stent integrity assessed by flat plate x-rays, and (3) acute death, amputation and TLR events evaluated at 24 and 36 months post implantation. Secondary endpoints are descriptive and life table and Kaplan-Meier estimates will be used for time to event variables such as major adverse events and death through 36 months.

   The sponsor was advised that the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.

   The sponsor is required to submit PAS Progress Reports annually. The reports should clearly be identified as Post-Approval Study Report. Two copies of the study, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by

PMA Order"
(www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2).

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.